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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,333	12/15/2004	Yukio Goto	TB00005	1238
20462	7590	08/21/2007	EXAMINER	
SMITHKLINE BEECHAM CORPORATION			JIANG, DONG	
CORPORATE INTELLECTUAL PROPERTY-US, UW2220				
P. O. BOX 1539			ART UNIT	PAPER NUMBER
KING OF PRUSSIA, PA 19406-0939			1646	
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			08/21/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/518,333	GOTO ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 02 July 2007.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) 2,4 and 6-9 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,3 and 5 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-9 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

## **DETAILED OFFICE ACTION**

Applicant's amendment filed on 02 July 2007 is acknowledged and entered. Following the amendment, claims 1, 3 and 5 are amended.

Currently, claims 1-9 are pending, and claims 1, 3 and 5 are under consideration.

### **Withdrawal of Objections and Rejections:**

The scope of enablement rejection of claims 1, 3 and 5 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's amendment.

The prior art rejection of claims 1, 3 and 5 under 35 U.S.C. 102(b) as being anticipated by Coleman et al. (WO 97/24441) is withdrawn in view of applicant's amendment.

### **Formal Matters:**

#### ***Claims***

Claim 5 remains objected to as being dependent upon, in part, a non-elected claim, claim 4. The applicant is required to rewritten the claim to read upon only the elected claims.

### **Rejections under 35 U.S.C. §112:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for the recitation "*consisting of at least* 90% identity to ..." because it is unclear whether it means that the identity is equal to 90% ("consisting of"), or more than 90% ("at least"). The metes and bounds of the claim, therefore, cannot be determined.

Claim 5 is included in this rejection because it is dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

**Rejections Over Prior Art:**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman et al, WO 97/24441 (provided by applicants), and further in view of Ushio et al. (J. Immunol., 1996, 156 :4274-79).

The teachings of Coleman were reviewed in the last Office Action. Coleman discloses a human IGIF-2 polypeptide, which amino acid sequence of SEQ ID NO:2 has 193 residues, and the amino acids 36-193 is 100% identical to the present SEQ ID NO:1 (157 amino acids). Additionally, Coleman teaches that said polypeptide can be used for treating diseases/conditions including, among others, Crohn's disease or other inflammatory bowel diseases (the paragraph bridging pages 35 and 36). Coleman does not teach a polypeptide *consisting of* 90% identity to SEQ ID NO:1 (157 amino acids).

Ushio teaches a polypeptide of the human IGIF (now known as IL-18), and a method of recombinant expression of the polypeptide (page 4275, the middle of the left column), wherein the precursor IGIF polypeptide comprises 193 amino acids (Figure 1), which sequence is 100% identical to Coleman's polypeptide of SEQ ID NO:2. Additionally, Ushio teaches that the N-terminal amino acid sequence for the natural IGIF starts at the 37<sup>th</sup> residue (page 4276, the last paragraph of the left column), thus, Ushio's natural IGIF is 100% identical to the present SEQ ID

NO:1. Further, Ushio teaches that the recombinant precursor IGIF (193 amino acids) shows little biologic activity (page 4276, the last paragraph of the right column). Additionally, Ushio teaches the biologic functions of the IGIF including induction of IFN- $\gamma$  (Figure 5B), and activation of cytotoxic NK cells (Figure 7).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the active (natural) form of IGIF (157 amino acids) taught by Ushio in a method of treatment of diseases such as IBD as indicated by Coleman because Ushio teaches that the precursor IGIF (193 amino acids) shows little biologic activity. The person of ordinary skill in the art would have been motivated to use the natural form of IGIF for disease treatment because it is biologically active, as indicated by Ushio, and reasonably would have expected success because Ushio has demonstrated that the natural form of IGIF exhibited the biologic functions such as induction of IFN- $\gamma$  production.

**Conclusion:**

No claim is allowed.

**Advisory Information:**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



LORRAINE SPECTOR  
PRIMARY EXAMINER

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
8/8/07